DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Hamamatsu Photonics K.K.
% Mr. Jeffrey K. Shapiro
Hyman, Phelps and McNamara
700 Thirteenth Street, North West, Suite 1200
Washington, District of Columbia 20005

July 31, 2015

Re: K143219
Trade/Device Name: NIRO-200NX
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD, DQA
Dated: July 6, 2015
Received: July 6, 2015

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143219

Device Name
Hamamatsu NIR0-200NX

Indications for Use *(Describe)*
The NIR0-200NX is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIR0-200NX should not be used as the sole basis for diagnosis or therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
NIRO-200NX

Submitter Name: Hamamatsu Photonics K.K.

Submitter Address: 812 Joko-cho, Higashi-ku, Hamamatsu City, 431-3196, JAPAN

Contact Person: Susumu Suzuki

Phone Number: 81-53-431-0124

Fax Number: 81-53- 431-0148

Date Prepared: July 24, 2015

Device Trade Name: NIRO-200NX

Device Common Name: Oximeter

Product Code: MUD

Subsequent Product Code: DQA

Classification: Class II per 21 C.F.R. § 870.2700

Predicate Device:
Somanetics INVOS 5100C (K082327),
Hitachi ETG-100 (K011320) and ETG-4000 (K042501)

Device Description: The NIRO-200NX is a reusable piece of equipment that uses near infrared light for non-invasive measurement of hemoglobin oxygen saturation and relative levels of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes. The patient probes are applied to the skin over the tissue of interest. The probes have a light source and 2 photodiodes, one closer to the light source and one further away from the light source. The 2 photodiodes detect the light transmitted through the patient's tissue. The detected light is analyzed with the known light absorption characteristics of oxyhemoglobin and deoxyhemoglobin. The amount of light detected by the photodiode closer to the light source is subtracted from the light detected by the farther photodiode. The result is then used to calculate the hemoglobin oxygen saturation. Also, by measuring the changes in light detected from one of the

photodiodes, the relative levels of oxygenated hemoglobin and deoxygenated hemoglobin are calculated.

Intended Use: The NIRO-200NX is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX should not be used as the sole basis for diagnosis or therapy.

Performance data: The following electrical, performance, and clinical literature has been conducted with and reported using the NIRO-200NX and is described in the 510(k) submission. All tests and literature demonstrate that the device functions as intended and performs equivalently to the predicate devices.

1. Electrical per IEC 60601-1

2. Electromagnetic Compatibility per IEC 60601-1-2

3. Light Emitting LED Product per IEC 60825-1 (Class1 LED product)

4. Bench data demonstrating that NIRO-200NX performs equivalently in tissue phantoms compared to the predicate devices.

5. The NIRO-200NX has been sold and used clinically for more than 4 years in Japan and Europe without any reported adverse events. A review of the published literature concludes that the device worked as intended by safely being used as an adjunct monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes. Specifically, clinical literature demonstrated that NIRO-200NX and the predicate INVOS performed equivalently in a clinical setting. In addition, clinical literature was provided to show that NIRO-200NX has been used successfully in infants.

Substantial Equivalence:

The predicate devices are ETG-100 (K011320), ETG-4000 (K042501), and INVOS 5100C (K082327).

The proposed NIRO-200NX and the predicate devices all have the same intended use: as Oximeters. The proposed and predicate devices also have similar indications for use. The proposed and predicate devices all have the same principles of operation: they all measure levels of oxygen based on light measurements taken from the surface of intact tissue on the outside of a patient's body. The NIRO-200NX and the predicate

devices have similar technological characteristics, and any minor differences do not raise different questions of safety or efficacy, as confirmed by Hamamatsu's testing and validation activities described in this submission, including EMC, electrical safety, and laser safey testing in accordance with IEC 60601-1-2 (2008), IEC 60601-1 (2005), and IEC 60825-1 (1993 + A1 (1997) + A2 (2001), respectively. Hamamatsu followed the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005," to classify the NIRO-200NX software as a "moderate level of concern." The software was verified and validated, and the software verification and validation documents were prepared and presented in accordance with FDA's guidance document.

Further, NIRO-200NX is at least as safe and effective as the predicate devices as demonstrated by the results of bench and clinical data reported in literature, including the phantom study and the published clinical literature described below.

Phantom Study

Hamamatsu performed a phantom study to compare performance of the proposed and predicate devices side by side in a simulated model. The results of the study demonstrated that performance of the NIRO-200NX is substantially equivalent to the performance of INVOS at measuring regional hemoglobin oxygen saturation; and ETG at measuring relative levels of oxygenated hemoglobin and deoxygenated hemoglobin.

Published Clinical Literature

Bickler et al reported on a clinical study that directly compared the performance of NIRO-200NX and INVOS to each other (along with several other cleared devices) and to results of a blood draw in a clinical setting. The evaluation was performed in 23 individuals with 181 individual measurements taken for INVOS and 179 individual measurements taken for NIRO-200NX. The study subjects included those with light, intermediate and dark skin. The study results showed substantially equivalent performance between NIRO-200NX and INVOS in a clinical setting at measuring regional hemoglobin oxygen saturation.

The above information leads to the conclusion that the NIRO-200NX is substantially equivalent to the predicate devices. The Substantial Equivalence comparison chart is found below in Table 1.

Table 1

	NIRO-200NX Hamamatsu Photonics K.K. (New Device)	ETG-100 and ETG-4000 Hitachi Medical Systems America, Inc (ETG-100 for K011320) (ETG-4000 for K042501)	INVOS 5100C Somanetics Corporation (K082327)
INTENDED USE	Oximeter (MUD, DQA)	Oximeter (DQA)	Oximeter (MUD)
INDICATIONS FOR USE	The NIRO-200NX is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX should not be used as the sole basis for diagnosis or therapy.	A) K011320 The intended use of the ETG-100 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin. B) K042501 The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.	The noninvasive INVOS 5100C is intended for use as an adjunct monitor or regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5kg at risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual. The clinical value of trend data has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

	NIRO-200NX Hamamatsu Photonics K.K. (New Device)	ETG-100 and ETG-4000 Hitachi Medical Systems America, Inc (ETG-100 for K011320) (ETG-4000 for K042501)	INVOS 5100C Somanetics Corporation (K082327)
PRINCIPLE OF OPERATION	The patient probe consists of a light source (3 wavelengths) and 2 detectors, and it is applied to the skin over the tissue of interest. Hemoglobin oxygen saturation (TOI) is calculated from the differences of the amount of detected lights by the 2 detectors. Relative value of the total hemoglobin (nTHI) is calculated by the same methods as that of TOI. Relative levels of oxygenated, deoxygenated and total hemoglobines (ΔO2Hb, ΔHHb and ΔcHb) are calculated from the changes in the amount of the detected lights by one detector.	The patient probe consists of a light source (2 wavelengths) and 1 detector, and it is applied to the skin over the tissue of interest. Relative levels of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin are calculated from the changes in the amount of the detected lights by one detector.	The patient probe consists of a light source (2 wavelengths) and 2 detectors, and it is applied to the skin over the tissue of interest. Hemoglobin oxygen saturation (rSO2) is calculated from the difference of the amount of detected lights by the 2 detectors.

TECHNOLOGICAL CHARACTERISTICS

	NIRO-200NX Hamamatsu Photonics K.K. (New Device)	ETG-100 and ETG-4000 Hitachi Medical Systems America, Inc (ETG-100 for K011320) (ETG-4000 for K042501)	INVOS 5100C Somanetics Corporation (K082327)
Light Source Device Wavelength Safety Class	LED (Light Emitting Diode) 3 wavelengths Class I	LD (Laser Diode) 2 wavelengths Class I	LED 2 wavelengths Class I
Light Detector	Photodiode	Photomultiplier Tube	Photodiode
Measurement Method	2 Point Detection Method for Hemoglobin Oxygen Saturation (TOI) and Relative value of the total hemoglobin (nTHI)	Not applicable. Not measured by this device.	2 Point Detection Method for Hemoglobin Oxygen Saturation (rSO2)
	1 Point Detection Method for Relative Levels of Hemoglobins	1 Point Detection Method for Relative Levels of Hemoglobins	Not applicable. Not measured by this device.
Patient Contact	Non-Invasive	Non-Invasive	Non-Invasive
EMC and Electrical Safety	Passed applicable safety testing	Passed applicable safety testing	Passed applicable safety testing